

Election/Restrictions

1. The first action on the merits mailed February 15, 2008 is vacated for the reasons delineating in the accompanying Interview Summary. A new Action is set forth herein.

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-9, drawn to a method for treating a solid tumor that expresses at least one cellular marker and administering to the tumour a ligand of said marker.

Group II, claim(s) 10-13, drawn to a method of diagnosing solid tumors comprising identifying a cell marker.

Group III, claim(s) 14, drawn to a method for screening for ligands of a cellular marker.

Group IV, claim(s) 15, drawn to a method of preparing a medicament comprising a ligand of a cellular marker for the treatment of a solid tumors.

3. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: U.S. Patent number 7,105,682 B2 (filed January 10, 2002), as evidenced by Guenther et al. (Pathology-Research and Practices 201: 649-663, 2005) teaches a method of treating solid neoplasms, such as bone cancers and osteosarcomas with a pharmaceutical composition comprising alemtuzumab, a ligand of cellular marker CDw52 in combination with chemotherapy, see abstract; column 36, lines 9-29; column 46, lines 1-17; and column 48, lines 26-28. This disclosure, as well as Guenther evidences it is art known cellular marker CDw52 is expressed on bone tumors, giant cell tumors and osteosarcomas, see page 656, Immunohistochemical...section, 2nd paragraph; and page 660, 2nd column, 1st full paragraph.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- a. CDw52;
- b. Claudin 7;
- c. Ephrin A1;
- d. AMFR;
- e. MME; and
- f. FGFR3.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

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The methods read on the implementation of separate and distinct ligands for the treatment of solid cancer.

The following claim(s) are generic: 2-9 and 11-13.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each ligand which corresponds to the separate and distinct cellular markers differs in composition, conformation and expression. For example, ligands for CDw52 are known such as alemtuzumab, whereas Claudin 7 ligands have not all been identified, nor characterized and largely unknown.

Applicants are reminded to elect one species with the election of one of the four Groups.

4. A telephone call was made to David R. Saliwanchik on February 20, 2008 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the

record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.

21 February 2008

/Alana M. Harris, Ph.D./

Primary Examiner, Art Unit 1643